

Serial No. : 10/675,254
Docket No. : 49288.0800

REMARKS

Applicants reply to the Final Office Action mailed on May 12, 2006 within two months. Thus, Applicants request an Advisory Action, if necessary. Claims 1-4 and 6-17 were pending in the application and the Examiner rejects claims 1-4 and 6-17. Applicants cancel claims 3 and 11-13 without prejudice to filing other applications with one or more claims having similar subject matter. Support for the amendments may be found in the originally-filed specification, claims, and figures. No new matter has been introduced by these amendments. Reconsideration of this application is respectfully requested.

The Examiner rejects pending claims 1-4, 6-13, 16 and 17 as being obvious over WO 99/39624 ('624) in view of US 6,673,604 ('604). Applicants respectfully traverse this rejection.

As acknowledged by the Examiner, '624 fails to teach a method of injecting cells into an individual at a predetermined rate. Applicants assert that, although '604 allegedly discloses the benefit of injecting muscle cells into a heart, '604 fails to disclose injecting the cells at a "predetermined range of velocity of at least about 1 ml/min and less than, or equal to about 20 ml/min," (emphasis added) as recited in amended claim 1.

The Examiner also alleges that it is within the capability of one of ordinary skill in the art to modulate the rate of drug administration in manner that it is responsive to physiological signals, based on the disclosure of claim 45 of '624. Applicants respectfully disagree because there does not appear to be any teaching in the cited references to maintain the activity of injected cells via the claimed predetermined range of velocity of at least about 1 ml/min and less than, or equal to about 20 ml/min. Thus, the Applicant submits that the claimed invention is unobvious over cited references '624 in view of '604.

The Examiner rejects claims 1-4 and 6-11 as being anticipated by US 5,690,618 ('618), and claims 12, 13, 16 and 17 as being obvious over US 5,690,618 in view of US 6,673,604. Applicants respectfully traverse this rejection.

The Examiner contends that '618 discloses an electronic syringe capable of delivering active agents with a flow rate falling within the claimed range of "about 1 ml/min." However, the Examiner also acknowledges that '618 fails to teach injecting cell-based pharmaceuticals into the heart of a subject, and that '604 allegedly complements the disclosure of '618, thus anticipating the present application or rendering the claimed invention obvious.

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Applicants assert that the claimed invention as defined by amended claim 1 is novel over '618 as the reference fails to disclose the feature of a "cell." Applicants amend pending claims 1 and 17 to recite "a liquid drug contain a cell," (emphasis added). Support for the amendments can be found in, for example, paragraph [0026] of US 2005/0070874 A1. The claimed predetermined range of velocity of "at least about 1 ml/min and less than, or equal to about 20 ml/min" (emphasis added) also further distinguishes the claimed invention from the device disclosed in '618. As such, the claimed invention is novel over the '618 reference.

With regard to the Examiner's assertion that it would have been obvious to those skilled in the art to inject cells in a manner consistent with the method of '618, Applicants assert that the flow rate disclosed in '618 is meant to reduce the discomfort of patients when syringes are used to inject active agents into these patients (column 6, lines 14-26 of US Patent 5,690,618). On the contrary, the claimed predetermined range of velocity of "at least about 1 ml/min and less than, or equal to about 20 ml/min" (emphasis added) is designed to maintain the viability or activity of the cells. As such, the skilled artisan attempting to conceive the claimed invention through the disclosure of '618 would not have been effectively instructed to maintain the activity of the cells. Therefore, Applicants assert that the claimed invention is unobvious over '618 in light of '604.

The Examiner rejects pending claims 1-4, 6-13, 16 and 17 as failing to comply with the written description requirement. Applicants respectfully traverse this rejection.

With regard to the rejection of pending claim 16, in order to expedite the allowance of the present application, Applicants delete the term "prophylaxis" from pending claim 16. Thus, Applicants submit that pending claim 16 is now in condition for allowance.

With regard to the Examiner's assertion that the recitation "about 1 ml/min" in pending claim 1 does not satisfy the written description and/or the enablement requirements, Applicants amend pending claims 1 and 17 by clarifying the claimed predetermined range of velocity as being "at least about 1 ml/min and less than, or equal to about 20 ml/min" (emphasis added). Support for the amendment can be found in, for example, paragraph [0017] of US 2005/0070874 A1. Therefore, Applicants assert that the claimed invention satisfies all the requirements for written description and enablement.

The Examiner next rejects claims 1-4, 6-13 and 16 as constituting a provisional, non-statutory obviousness-type double patenting over claims 1-13 and 16 of co-pending application number 10/954,639. Applicants respectfully traverse this rejection. However, to expedite

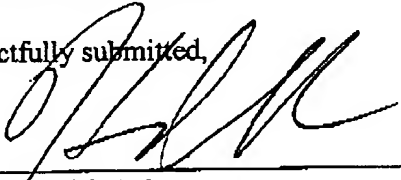
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prosecution of this matter, Applicants submit the attached terminal disclaimer in compliance with 37 C.F.R. 1.321.

In view of the above remarks and amendments, Applicants respectfully submit that all pending claims properly set forth that which Applicants regard as their invention and are allowable over the cited references. Accordingly, Applicants respectfully request allowance of the pending claims. The Examiner is invited to telephone the undersigned at the Examiner's convenience, if that would help further prosecution of the subject Application. Applicants authorize and respectfully request that any fees due be charged to Deposit Account No. 19-2814.

Respectfully submitted,

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